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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,550	01/25/2002	Brett P. Monia	ISPH-0625	5088

7590 08/13/2002

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	6

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE

Office Action Summary	Application No.	Applicant(s)	
	10/057,550	MONIA, BRETT P.	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *2 and 3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-14* is/are rejected.

7)☒ Claim(s) *15-20* is/are objected to.

8)☒ Claim(s) *2 and 3* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the gene transcripts listed in claims 1-4 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such transcripts to be searched in a single application. Under this policy, up to 10 independent and distinct nucleotide transcripts will be examined in a single application. See MPEP 803.04 and 2434.

Claims 1-4 claim any oligonucleotide sequence that is targeted to and inhibits the expression of human raf mRNA. Although the claims are directed to antisense sequences that target and modulate expression of the class of raf gene subtypes consisting of A-raf, B-raf, or c-raf, the gene transcript targets are the subject of the search and are considered to be unrelated, since each transcript specified is structurally and functionally independent and distinct for the following reasons: each gene transcript has a unique nucleotide sequence, each transcript has a different function within its operative pathway, and the pathways themselves often if not always target different endpoint proteins. Furthermore, a search of more than one (1) of the raf subtype targets claimed in claims 1-4 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed raf subtypes. In view of the foregoing, one (1) subtype transcipt is considered to be a reasonable number of genes for examination. Accordingly, applicants are required to elect one (1) transcipt from claims 1-4.

During a telephone conversation with Ms. Kathleen Tyrell on July 20, 2002, a provisional election was made with traverse to prosecute the invention of sequences that target and inhibit the human c-raf transcript, which includes claim 1 as it relates to the human c-raf transcript, and claims 4-20. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2 and 3, and claim 1 as related to claims 2 and 3, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, and 4-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7 and 9-11 of U.S. Patent No. 5,563,255. Although the conflicting claims are not identical, they are not patentably distinct from each other because they directly anticipate the instantly claimed compositions. Claims 1

and 4-8 of the instant application are drawn to compounds that specifically hybridize and inhibit human c-raf, wherein the target region of said c-raf may consist of the translation initiation site, 3' untranslated region, or 5' untranslated region, wherein said compounds may contain phosphorothioate linkages, modified sugar moieties, or at least one 2'-deoxynucleotide.

Claims 1-12 of U.S. Patent No. 5,563,255 are drawn to compounds that specifically hybridize and inhibit human c-raf, wherein the target region of said c-raf may consist of the translation initiation site, 3' untranslated region, or 5' untranslated region, wherein said compounds may contain phosphorothioate linkages, modified sugar moieties, or at least one 2'-deoxynucleotide.

Claims 1, and 4-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, and 20 of U.S. Patent No. 5,952,229 in view of U.S. Patent No. 5,985,558. Claims 1, 4-10 and 12 of the instant application are anticipated by the above listed claims of U.S. Patent No. 5,952,229, while claim 11 would have been obvious to one of ordinary skill in the art.

Claims 1 and 4-9 of the instant application are described as relied upon above. Claims 10-13 are drawn to pharmaceutical compositions comprising c-raf targeted antisense oligos, wherein said pharmaceutical compound also comprises a chemotherapeutic agent, or wherein a method is claimed of inhibiting the expression of c-raf in cells or tissues using the claimed compounds, or wherein the expression of c-raf is abnormal.

Claims 1-6, 8, and 20 of U.S. Patent No. 5,952,229 teach compounds that specifically hybridize and inhibit human c-raf, wherein said compounds may contain phosphorothioate linkages, modified 2'-sugar moieties. The claims are also drawn to compositions comprising c-raf targeted antisense oligos in a pharmaceutically acceptable carrier, or wherein a method is claimed of inhibiting the expression of c-raf in cells or tissues using the claimed compounds, or wherein the expression of c-raf is abnormal.

U.S. Patent No. 5,952,229 does not teach the antisense oligos of above in a pharmaceutically acceptable carrier that also comprises a chemotherapeutic agent. The specification of U.S. Patent No. 5,985,558 teaches antisense oligos in a pharmaceutical carrier that may also comprise a chemotherapeutic agent.

It would have been obvious to one of ordinary skill in the art to combine a chemotherapeutic agent as taught by U.S. Patent No. 5,985,558 with the instantly claimed antisense oligos in a pharmaceutical carrier. One or ordinary skill in the art would have been motivated to do so, since the '229 patent teaches that the instantly claimed antisense oligos can be used to target malignant tumors, and since chemotherapeutic agents are used to treat cancers.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,090,626. This is a double patenting rejection.

Allowable Subject Matter

Claims 15-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

J. Douglas Schultz, PhD
August 2, 2002